4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0086]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Potential Tobacco Product Violations Reporting Form

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0716. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Potential Tobacco Product Violations Reporting Form--(OMB Control Number 0910-0716)--Extension

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111-31) into law. The Tobacco Control Act amended section 201 et seq. of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321 et seq.) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. FDA is requesting an extension of OMB approval for the collection of information to accept consumer and other stakeholder feedback and notification of potential violations of the FD&C Act, as amended by the Tobacco Control Act.

FDA created a Tobacco Call Center (with a toll-free number: 1-877-CTP-1373). Callers are able to report potential violations of the Tobacco Control Act, and FDA will conduct targeted followup investigations based on information received. When callers report a violation, the caller will be asked to provide as much certain information as they can recall, including: The date the potential violation occurred; product type (e.g., cigarette, smokeless, roll-your-own); tobacco brand; potential violation type; type of potentially violative promotional materials; who potentially violated; and the name, address, phone number, and email address of the potential violator. The caller will also be asked to list the potential violator's Web site (if available), describe the potential violation, and provide any additional files or information pertinent to the potential violation.

FDA currently provides a form that may be used to solicit this information from the caller (Form FDA 3779, Potential Tobacco Product Violations Report), and seeks renewal of Form FDA 3779. This form is posted on FDA's Web site. The public and interested stakeholders are also able to report information regarding possible violations of the Tobacco Control Act through the following methods: Calling the Tobacco Call Center using the Center for Tobacco Products' (CTP) toll-free number; using a fillable Form FDA 3779 found on FDA's Web site; downloading a PDF version of the form to send via email or mail to FDA; requesting a copy of Form FDA 3779 by contacting CTP and sending by mail to FDA; and sending a letter to FDA's CTP. The public and interested stakeholders will also be able to report information regarding possible violations of the Tobacco Control Act in the future using FDA's tobacco violation reporting smartphone application.

In the Federal Register of February 18, 2014 (79 FR 9216), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity and Form FDA 3779	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Reporting violations of the FD&C Act, as amended by the Tobacco Control Act, by telephone, Internet form, mail, smartphone application, or email.	400	2	800	0.25 (15 minutes)	200

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that submitting the information (by telephone, Internet, mail, smartphone application, or email) will take 0.25 hours (i.e., 15 minutes) per response. FDA estimates the number of annual respondents to this collection of information will be 400, who will each submit 2 reports by telephone, Internet, mail, smartphone application, or email. This estimate is based

on the rate of reporting through Form FDA 3779, reports received from FDA's toll-free telephone number and email address, and FDA experience. Each report is expected to take 0.25 hours to complete and submit; therefore, total burden hours for this collection of information is estimated to be 200 hours (800 responses × 0.25 hours per response). The total burden hours for this collection have decreased by 50 hours (from 250 to 200) because the number of estimated respondents decreased from 1,000 to 400, and the annual responses are expected to drop from 1,000 to 800. Based on past submissions to FDA, the number of estimated annual respondents is expected to decrease from 1,000 to 400 and each respondent's number of submissions is expected to increase from 1 to 2 annually. Therefore, the number of responses is expected to decrease from 1,000 to 800 annually (400 respondents × 2 responses).

Dated: May 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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